

OBJECTIVES

Upon completion of this module, without reference material, the trainee will be able to

1. Identify the types of cooked sausage products that are covered under Fat and Added Water requirements.
2. Identify the types of cooked sausage products that are covered under Added Water requirements.
3. Describe the method of sample selection from a lot when the sample is submitted to an FSIS laboratory or an accredited laboratory.
4. Interpret the “percent fat” and “percent fat plus added water” action criteria tables.
5. Classify example laboratory results and correctly plot values on an FSIS Form 7130-3.
6. Specify the procedure frequency for
 - Normal sampling.
 - Tightened sampling.
7. Identify who initiates a switch from normal sampling and acceptance criteria to tightened sampling and acceptance criteria.
8. State FSIS action while on “normal” acceptance criteria and the sample analysis is
 - Zone A.
 - Zone B.
 - Seventh consecutive result above Zone A.
 - Zone C (second consecutive).
 - Zone D.
 - Zone E.
9. State FSIS action while on “tightened” acceptance criteria and the sample analysis is
 - Zone A (fewer than 4 consecutive Zone A results).
 - Zone A (fourth consecutive Zone A result).
 - Zone B.
 - Zone C.
 - Zone D.
 - Zone E.
10. Specify what requirements must be met in order for the establishment to be switched from tightened sampling and acceptance criteria back to normal sampling and acceptance criteria.
11. Identify the number of samples that must be selected when sampling a failed lot.

12. State the action taken by the inspection program employee when sample results from a failed lot do not average in Zone A.
13. Define the following terms.
 - Sample
 - Lot
 - Failed lot
 - Unsampled lot
 - Sampled lot
 - Zones
 - Compliance factor
 - Subsequent production

INTRODUCTION

Cooked sausages are those sausages produced under §319.140, §319.180, §319.181, and §319.182 of the regulations. The Federal Meat Inspection Regulations limit the amount of fat, added water, or fat-plus-added water that may be present in cooked sausages.

§319.180 states “Frankfurter, frank, furter, hot dog, wiener, vienna, bologna, garlic bologna, knockwurst, and *similar cooked sausages* are comminuted, semi-solid sausages prepared from one or more kinds of raw skeletal meat or raw skeletal muscle meat and raw or cooked poultry meat, and seasoned and cured, using one or more of the curing agents in accordance with §318.7(c)(4) of this chapter. They may or may not be smoked. The finished products shall not contain more than 30% fat. Water or ice, or both, may be used to facilitate chopping or mixing or to dissolve the curing ingredients but the sausage shall contain no more than 40% of a combination of fat and added water.”

§319.181 states “Cheesefurters and *similar products* are products in casings which resemble frankfurters except that they contain sufficient cheese to give definite characteristics to the finished article. These products shall contain no more than 40% of a combination of fat and added water, and no more than 30% fat and shall comply with the other provisions for cooked sausages that are in Part 319, Subpart G of the regulations.”

Other cooked and smoked sausages covered under §319.140, such as Polish sausage, beef salami, and cotto salami are usually coarse ground. In these products, where fat is visible to the consumer, there is no fat content limitation but added water is limited to 10% in the finished product.

Braunschweiger, liverwurst, and liver sausage are characterized by containing at least 30% liver and are usually cooked in impervious casings. These products are covered under §319.182 and are limited to 10% added water in the finished product.

Cooked mettwurst, cooked bratwurst, bierwurst, and blood and tongue sausage are just a few of the specialty sausages listed in the Standards and Labeling Policy Book and are limited to 10% added water in the finished product.

Within §319.180 and §319.181 there are types of products specifically listed. In §319.180, products such as frankfurter, frank, furter, hot dog, wiener, vienna, bologna, garlic bologna, and knockwurst are listed. In §319.181, cheesefurters are listed. Both sections also contain a catchall phrase. For instance, §319.180 contains the phrase “and similar sausages” and §319.181 contains the phrase “and similar products.” What is the meaning of “similar sausages” or “similar products?” What is the logic behind such phrases?

Before we can define “similar sausages” and “similar products,” we must understand how the types of products specifically listed are manufactured. Basically, “listed” sausages have a number of things in common. They are

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1. Finely ground (chopped),
2. Cured,
3. Stuffed, and
4. Smoked and cooked or cooked.

The phrases “similar sausages” as used in §319.180 and “similar products” as used in §319.181 are included to cover any sausages or products that resemble those specifically listed. For example, a product labeled “Knoblough Sausage” is not listed. If this type of sausage is finely ground or emulsified to the point where *any* fat in the product is not distinguishable to the consumer and it is cooked or cooked and smoked, it would be limited to not more than 30% fat or a combination of 40% fat and added water. If cheese is added in sufficient amounts to characterize the product, the product is still limited to 30% fat or a combination of 40% fat and added water and is covered under §319.181.

If any doubt arises about a specific product name, contact the Label Review Branch through channels for a ruling.

FSIS inspection program employees are responsible for ensuring that cooked sausage products are in compliance with regulatory requirements and that no adulterated or misbranded products are distributed for sale. The principal methods used by FSIS to ensure that these products are not adulterated or misbranded are observation of their formulation and preparation, and the routine submission of samples to an FSIS laboratory or designated accredited laboratory for fat and/or total moisture analyses. Added water is then determined in accordance with FSIS Directive 7140.2. The sample results are used in deciding whether process controls in the establishment are effective and whether product is consistently in compliance with regulatory requirements for fat and/or added water content. In other words, sample results are used to judge the *process* that produced the product. The product itself is a result of the process.

PRODUCT CONTROL

It is establishment management’s responsibility to control the process through process monitoring and ensure that the finished product is in compliance with regulatory requirements. Two *inspection approaches* are used to determine a cooked sausage product’s compliance with fat, fat-plus added water, or added water regulatory limits. These inspection approaches coupled with process observations are

- Lot inspection, and
- A Quality Control (QC) Program or Total Quality Control (TQC) System.

The end result is the same— product produced is in compliance.

LOT INSPECTION

- A. To ensure process control under lot inspection (when there is not a quality control program/system), the inspection program employee
1. Verifies the compliance of cooked sausage products with fat and added water content regulatory limits by taking samples of the products,
 2. Maintains records of samples and laboratory results,
 3. Takes appropriate action when sample results indicate noncompliance with the regulations, and
 4. Observes the production process.
- B. In order to properly select samples, an inspection program employee must understand the definition of a "lot".
1. A lot is all product produced from
 - One basic formulation or method of preparation,
 - One size and type container/casing, and
 - One shift.

Examples of formulations that would constitute different lots are

- ▶ A single meat,
- ▶ A single meat with byproducts,
- ▶ A single meat with extenders, and
- ▶ A single meat with byproducts and extenders.

One size refers to the diameter of the product. In order for products to be considered something other than one size (diameter), we *must* consider the process used to manufacture the product, i.e., cook time, cook temperature, chill time. For example, 12-to-1 franks probably would be cooked for a different length of time than 8-to-1. This would indicate two different lots since the size or diameter of product required a different cooking process. The shape or length of casing would have no bearing on the definition of size.

The shift is the hours the establishment operates with the same crew. If it operates from 6 a.m. to 2:30 p.m., with the same crew, that is a shift. If the same crew works from 6 to 6, that also is one shift.

Once you understand what a lot is, you are then ready to select a sample (when required).

Sampling Frequency

The inspection program employee will sample when

- A. Directed to by the Automated Data Processing (ADP) system of PBIS (scheduled procedure); or
- B. He/she suspects that violative product is being produced or has been produced (unscheduled procedure); or
- C. Directed to by supervision.

Note: You should contact your supervisor before sampling suspect product.

Under PBIS, the sampling frequency for

- ▶ Normal sampling and acceptance criteria is monthly (on the average) for all establishments.
- ▶ Tightened sampling and acceptance criteria is per shift for all establishments.

Sample Selection

- A. Lot inspection - sample is submitted to an *FSIS laboratory or an accredited laboratory*.

1. The FSIS inspection program employee will randomly select *three 1-pound units* from different portions of a single lot of unpackaged finished product. Do not composite the sample. Under normal sampling or tightened sampling, the sample represents all lots of product subject to the same standard as specified in §319.140, §319.180, §319.181, or §319.182. For example, if the sample was taken from a lot of cotto salami, that sample would also represent lots of beef salami, liverwurst, Polish sausage, mortadella, etc., produced during that same shift.

Similarly, if the sample was taken from a lot of franks, that sample would also represent lots of bologna, wieners, knockwurst, etc., produced during the same shift.

2. Submit the sample (three 1-pound units) accompanied by FSIS Form 10,600-1 to the laboratory. Identify each plastic bag with a label showing the production date, product name, lot number (if available), establishment number, and the last three digits of FSIS Form 10,600-1 that you submit with them. In addition, number the three 1-pound sample units ("1 of 3," "2 of 3," and "3 of 3"). Attach each label to the bag it identifies.

- B. Accreditation

If an establishment elects to use an outside accredited laboratory or has an accredited laboratory on its premises, the FSIS inspection program employee will

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1. Refer to the current list of accredited laboratories to determine if the laboratory is accredited. The list is posted in Microsoft Outlook's "All Public Folders" under "Accredited Laboratories."

The list is also maintained at the District Offices.

2. Ask establishment management to provide evidence that the laboratory they are using has current FSIS accreditation when he/she does not have access to Microsoft Outlook. Accredited laboratories have been issued certificates of accreditation valid for 1 year. The expiration date for each accreditation is shown on the certificate.

PBIS Application to the Control of Fat and Added Water Products

- A. All establishments start under "normal" sampling and acceptance criteria. As previously stated, the *normal sampling* frequency will be *monthly*. Cooked sausages with a fat-plus-added water limit and those with only an added-water limit are addressed in Activity 05 of the Inspection System Procedure (ISP) guide.

The ISP procedure for sampling cooked sausages is 05B01. The computer program (ADP system) schedules procedures on a random basis. So even though the frequency is identified as monthly, the inspection program employee should not expect procedure 05B01 to be scheduled the same day each month. In fact, the program is designed to generate 12 sample collection procedures over a year. That could mean that he/she might see procedure 05B01 more than once in a given month; conversely, he/she may not have it scheduled during a particular month. The inspection program employee should notify his/her supervisor if more than two months go by without procedure 05B01 being scheduled.

When procedure 05B01 is scheduled, the inspection program employee will perform it, i.e., select a sample (if product is available). He/she will circle the word "performed" on the procedure schedule. Then he/she will submit the sample, accompanied by FSIS Form 10,600-1, to the laboratory normally used. Normal acceptance criteria is used for the first sample and continues to be used as long as sample results meet the criteria in Part A.1 of Compliance Determination and Recommended Action section of this module (page 10).

- B. When sample results do not meet normal acceptable criteria, "tightened" sampling and acceptance criteria will be initiated by the inspection program employee using ISP procedure 05B02. Under *tightened sampling*, the procedure frequency is on a *per shift basis*. Each time the inspection program employee selects a tightened sample, he/she will record the procedure code and result code "a" on a blank procedure schedule to identify the procedure as an *unscheduled procedure*. The tightened acceptance criteria in Part B of Compliance Determination and Recommended Action section of this module (page 11) are used until sample results indicate that establishment management has regained control of the process and justifies a resumption of normal sampling and acceptance criteria.

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C. The fat and fat-plus-added water compliance factors are monitored independently of one another. For example, a product under tightened sampling and acceptance criteria for fat may be under normal sampling and acceptance criteria for fat plus added water. If a product is under tightened sampling and acceptance criteria for a certain compliance factor and the ADP system schedules a sample collection procedure for that product, the inspection program employee will:

1. Collect a sample from a lot,
2. Request an analysis for *all* compliance factors,
3. Circle "performed" on the procedure schedule for the procedure, and
4. Use the normal acceptance criteria for the compliance factor not under tightened sampling and acceptance criteria.

Compliance Determination and Recommended Action

Ranges of analytical results for samples, called "zones" are used to allow for inherent variations in the manufacturing process, finished product sampling, and analytical error. The fat sample result zones, combined fat-plus-added water sample result zones, and added water sample result zones are defined in FSIS Directive 7130.3 and listed on FSIS Form 7130-3 (See below). Under lot inspection, the inspection program employee determines what action to take by noting the zone (A, B, C, D, or E) in which the sample result falls, the results of previous sample analyses, and by consulting acceptance criteria.

Sample Result Zones for Cooked Sausage Products (Normal and Tightened Criteria)

Zone	Percent Fat plus Added Water	Percent Fat	Percent Added Water
A	40.0 – under	30.0 – under	10.0 – under
B	40.1 – 41.2	30.1 – 30.6	10.1 – 11.0
C	41.3 – 42.3	30.7 – 31.1	11.1 – 12.0
D	42.4 – 43.4	31.2 – 31.6	12.1 – 13.0
E	43.5 – over	31.7 – over	13.1 – over

Lot Inspection	
Decision Guideline	
When plant is under normal acceptance criteria	
<u>Last laboratory result is:</u> Zone A Zone B Zone C (nonconsecutive) 7 th consecutive result above Zone A Zone C (second consecutive) Zone D Zone E	<u>Action by inspection program employee</u> Product moves freely Continue on normal acceptance criteria File lab report Do not take action against shift's production Go to tightened acceptance criteria for next sampling Retain all product produced subsequent to the sampled shift Issue an NR Retain all product produced on sampled shift Go to tightened acceptance criteria Retain all subsequent production Issue an NR
Lot Inspection	
Decision Guideline	
When plant is under tightened acceptance criteria – Shift's production	
<u>Last laboratory result is:</u> Zone A (except for 4 th consecutive) Zone B Fourth consecutive Zone A Zone C Zone D Zone E	<u>Action by inspection program employee</u> Release product produced on the sampled shift Continue under tightened acceptance criteria Continue retention of subsequent production Return to normal acceptance criteria Product moves freely Retain all product from sampled lot Require: <ul style="list-style-type: none"> • Product to be reworked, or • Product to be resampled, or • Other FSIS approved disposal Continue under tightened acceptance criteria Retain subsequent production Issue an NR Note: Lots produced on shift <i>other</i> than the failed lot may be sampled under plant-requested sampling.

Lot Inspection	
Decision Guideline	
When plant is under tightened acceptance criteria – Individual lots	
<u>Last laboratory result is:</u>	<u>Action by inspection program employee</u>
Zone A (except for 4 th consecutive)	Release product the sampled lot Continue under tightened acceptance criteria Continue retention of subsequent production
Fourth consecutive Zone A	Return to normal acceptance criteria Product moves freely
Zone B Zone C Zone D Zone E	Continue to retain all product from sampled lot Require: <ul style="list-style-type: none"> • Product to be reworked, or • Product to be resampled, or • Other FSIS approved disposal Continue under tightened acceptance criteria Retain subsequent production Issue an NR

A. An FSIS inspection program employee's responsibility upon receipt of a sample analysis under *normal acceptance criteria* is as follows.

1. When the sample result is in Zone A; Zone B; nonconsecutive Zone C; less than the 7th consecutive result above Zone A, the process is considered in control.
 - No action is taken against product.
 - No entries are made on the procedure schedule.
 - No Noncompliance Record (NR) is issued.
 - The lab report is appropriately filed.
2. When the sample result is the 7th consecutive result above Zone A; the 2nd consecutive result in Zone C; or the 1st result in Zone D
 - No action is taken against sampled product on that shift.
 - "Tightened" acceptance criteria is applied to the next sample.
 - All product produced subsequent to the sampled shift is retained.

Note: Subsequent production includes product, which is still in the official establishment, that was produced after the date of the sampled shift up until establishment management was notified of inspection switching from normal to tightened sampling and acceptance criteria. These shifts or lots of product must be sampled and analytical results must meet tightened acceptance criteria for product to be released. However, the only analytical results used to return the establishment to normal sampling and acceptance criteria are those results from shifts or lots of product produced after the establishment was *notified* of the switch from normal to tightened sampling and acceptance criteria.

- An NR is issued, including
 - ▶ Sample results,
 - ▶ Calculations used to determine noncompliance,
 - ▶ Official control action, if applicable (retaining/tagging product), and
 - ▶ Description of tightened sampling plan to be applied.
- Noncomplying sample result is discussed with establishment management.

3. When the sample result is in Zone E

- All product produced on the sampled shift that is still in the plant is retained.
- Product from the sampled (failed) lot
 - ▶ May be reworked, relabeled, or shrunk.
 - ▶ May be sampled - 30 1-lb samples. (See Plant-Requested Sampling.)
 - ▶ May otherwise be disposed of if approved by FSIS officials.

Lots on the shift other than the failed lot are to be sampled. These lots are referred to as *unsampled lots*. (See Plant-Requested Sampling.)

- “Tightened” acceptance criteria are applied to the next sample.
- All product produced subsequent to the sampled shift is retained.

Note: Subsequent production includes product which is still in the official establishment that was produced after the date of the sampled shift up until establishment management was notified of inspection switching from normal to tightened sampling and acceptance criteria. These shifts or lots of product must be sampled and sample results must meet tightened acceptance criteria for product to be released. However, the only sample results used to return the establishment to normal sampling and acceptance criteria are those results from shifts or lots of product produced after the establishment was notified of the switch from normal to tightened sampling and acceptance criteria.

- An NR is issued, including
 - ▶ Sample results,
 - ▶ Calculations used to determine noncompliance,
 - ▶ Official control action, if applicable (retaining/tagging product), and
 - ▶ Description of tightened sampling plan to be applied.
 - Noncomplying sample results are discussed with establishment management.
- B. An FSIS inspection program employee's responsibility upon receipt of sample analysis under *tightened acceptance criteria* is as follows.

Note: Under tightened sampling and acceptance criteria, all production of like product must be retained pending laboratory analysis. Each shift's product must be sampled to be released. The establishment has two sampling options.

Option 1 - Shift's Production (One sample represents the entire shift's production.)

1. When the sample result is in Zone A (but less than 4th consecutive in Zone A) or Zone B
 - All product produced on the sampled shift is released.
 - "Tightened" acceptance criteria is continued.
 - Retention of subsequent production is continued.

Note: When the sample result is in Zone B, the count for the four consecutive Zone A results starts at one" again.
2. When the sample result is the 4th consecutive Zone A
 - Retained product is released.
 - Product is allowed to flow freely.
 - Tightened sampling and acceptance criteria ends. The next sample is under normal sampling and acceptance criteria.
 - Subsequent production is not retained.
 - Previous NRs associated with action criteria are closed out.

3. When the sample result is Zone C; Zone D; or Zone E

- Continue to retain entire shift's production represented by the sample.
- Product from the sampled (failed) lot
 - ▶ May be reworked, relabeled, or shrunk.
 - ▶ May be sampled - 30 1-lb samples. (See Plant-Requested Sampling.)
 - ▶ May otherwise be disposed of if approved by FSIS officials.

Lots on the shift other than the failed lot are to be sampled. These lots are referred to as *unsampled lots*. (See Plant-Requested Sampling.)

- "Tightened" acceptance criteria is continued for the next sample.
- Subsequent production continues to be retained.
- The count for the four consecutive Zone A results starts at "one" again.
- An NR is issued, including
 - ▶ Sample results,
 - ▶ Calculations used to determine noncompliance,
 - ▶ Official control action, if applicable (retaining/tagging product), and
 - ▶ Description of tightened sampling plan to be applied.
- Noncomplying sample results are discussed with establishment management.

Option 2 - Individual lot(s)

1. When the sample result is in Zone A (but less than 4th consecutive in Zone A)

- The product lot that was sampled is released.
- "Tightened" acceptance criteria is continued.
- Retention of subsequent production is continued.

2. When the sample result is the 4th consecutive Zone A

- Retained product is released.
- Product is allowed to flow freely.

- Tightened sampling and acceptance criteria ends. The next sample is under normal sampling and acceptance criteria.
 - Subsequent production is not retained.
 - Previous NRs associated with action criteria are closed out.
3. When the sample result is Zone B; Zone C; Zone D; or Zone E
- All product from the sampled (failed) lot continues to be retained.
 - ▶ Product may be reworked, relabeled, or shrunk.
 - ▶ Product may be sampled - 30 1-lb samples. (See Plant-Requested Sampling.)
 - ▶ Product may otherwise be disposed of if approved by FSIS officials.
 - “Tightened” acceptance criteria is continued for the next sample.
 - Subsequent production continues to be retained.
 - The count for the four consecutive Zone A results starts at “one” again.
 - An NR is issued, including
 - ▶ Sample results,
 - ▶ Calculations used to determine noncompliance,
 - ▶ Official control action, if applicable (retaining/tagging product), and
 - ▶ Description of tightened sampling plan to be applied.
 - Noncomplying sample results are discussed with establishment management.

Plant-Requested Sampling Procedures

Retained lots that could not be released under the previously described procedures may be sampled at the request of establishment management.

Note: Retained lots of product produced prior to the date the establishment is notified of a switch from normal to tightened sampling and acceptance criteria are *also* considered *unsampled* lots.

A. Sampling retained *unsampled* lots. The packer has two options.

Option 1. At the establishment’s request, the FSIS inspection program employee will randomly select a sample (three 1-pound units) from each of the unsampled lots produced on a shift. To release each lot the sample result must be in Zone A. If the sample result is in Zone B, Zone C, Zone D, or Zone E, the lot is considered a sampled (failed) lot and may be

- ▶ Reworked, relabeled, or shrunk.
- ▶ Sampled - 30 1-lb samples. (See Part B of this section.)
- ▶ Otherwise be disposed of if approved by FSIS officials.

Option 2. The establishment may group all the unsampled lots from each shift into *one lot* and request that the inspection program employee randomly select a single sample (three 1-pound units) from one of the lots to represent all of them. To release all of the lots the sample result must be in Zone A or Zone B. If the sample result is in Zone C, Zone D, or Zone E, the lots are considered sampled (failed) lots and may be

- ▶ Reworked, relabeled, or shrunk.
- ▶ Sampled - 30 1-lb samples. (See Part B of this section.)
- ▶ Otherwise be disposed of if approved by FSIS officials.

The selection, preparation, and submission of these samples are performed in the same manner as previously described in this module. **All samples must be submitted to an accredited laboratory at the establishment's expense.**

These sample results will not be used to return the establishment to normal sampling and acceptance criteria.

- B. Resampling retained *sampled (failed) lots*. At the establishment's request the inspection program employee, or a designated plant employee under program supervision, will randomly select 30 individual 1-pound samples from each failed lot. Each sample is analyzed individually. To release the failed lot, the 30 individual results must **average** Zone A, and no individual result may be in Zone E.

The selection, preparation, and submission of these samples are performed in the same manner as previously described in this module. **All samples must be submitted to an accredited laboratory at the establishment's expense.**

These sample results will not be used to return the establishment to normal sampling and acceptance criteria.

Required Records

The FSIS inspection program employee will keep a separate score sheet, FSIS Form 7130-3, to record sample results for each compliance factor:

- One score sheet for *total fat* - products covered by §319.180 and §319.181 of the Regulations.
- One score sheet for *fat plus added water* - products covered by §319.180 and §319.181 of the Regulations.

- One score sheet for *total added water* - products covered by §319.140 of the Regulations.

Only laboratory results from normal and tightened samples are to be recorded on the FSIS Form 7130-3. Do not record laboratory results from plant-requested samples on the FSIS Form 7130-3.

The following information is designed to help the inspection program employee properly record sample results on the score sheet, FSIS Form 7130-3, and to understand which sample results may be used to return the establishment to normal sampling and acceptance criteria for future sampling.

Four consecutive sample results in Zone A, taken under tightened acceptance criteria, will return the establishment to normal sampling and acceptance criteria.

As previously mentioned, the establishment may select one of two sampling options while under tightened sampling and acceptance criteria to get production released.

- When the plant chooses to have you sample *one lot* to represent the entire shift's production.

Record the sample result on the score sheet.

- When the plant chooses to have you sample *each lot* of the shift's production

Record the one result that has the highest percentage of total fat or the highest percentage of fat plus added water.

For example, assume the plant produces one formula of frankfurters, one formula of bologna, and one formula of knockwurst (three lots). The sample results for today's production are

Lot 1 (frankfurters): 29.2% total fat and 39.2% fat plus added water (Zone A),

Lot 2 (bologna): 29.1% total fat and 39.9% fat plus added water (Zone A), and

Lot 3 (knockwurst): 30% total fat and 40% fat plus added water (Zone A).

Record the results from Lot 3 (knockwurst) as the Zone A on the score sheet.

If any sample results are in Zones B, C, D, or E, record the one that is the most violative.

Even though the sample results for all three lots were in Zone A, *only one* sample result may be used from *each* shift to count toward the four consecutive Zone A results necessary to return the establishment to normal sampling and acceptance criteria.

Instructions for Completing FSIS Form 7130-3

- Step 1.** Check the “Added Water,” “Total Fat,” or “Total Fat Plus Added Water” block to identify which laboratory results you will be recording on this score sheet.
- Step 2.** Enter the establishment number.
- Step 3.** On the “ITEM” line, enter the type of product that was sampled.
- Step 4.** On the “LOT #” line, enter the lot number, if known.
- Step 5.** On the “DATE PRODUCED” line, enter the date the product was produced, e.g., 10/4/97.
- Step 6.** On the “SAMPLE NO.” line, enter the three-digit sample number, preceded by the Establishment #.
- Step 7.** On the “RESULT %” line, enter the percent of total fat, percent of total added water, or percent of fat plus added water.
- Step 8.** Use an “X” to indicate whether the sample was taken under **normal** or **tightened** acceptance criteria. (The “X” should fill the entire box.)
- Step 9.** Use an “X” to indicate which zone the laboratory results fall into. (The “X” should fill the entire box.)

QUALITY CONTROL (QC) PROGRAM OR TOTAL QUALITY CONTROL (TQC) SYSTEM

If establishment management wants to do their own monitoring for fat, fat-plus-added water, or added water in their cooked sausage products, they may develop an effective quality control program or system. The only requirements for the program or system are that it shall include detailed information on the:

- raw material control
- critical check or control points
- nature and frequency of tests to be made
- charts and records that will be used
- length of time such charts and records will be maintained in the custody of the official establishment
- limits which will be used and points at which corrective action will be taken to prevent recurrence of a loss of control
- nature of the corrective action – ranging from least to most severe

The establishment may include additional requirements as necessary to meet specific needs.

The program or system must ensure the process is in control and that applicable label limits are being met. Process control is determined by generally recognized statistical process control procedures.

The written program or system and the data and information generated by the program or system must be made available to inspection program employees.

FSIS inspection personnel should *not* request copies of these records nor maintain establishment records in the official files.

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When the establishment has a quality control program or system to verify the control of fat, fat-plus-added water, or added water compliance in cooked sausage products, inspection's responsibility does not cease. The inspection program employee will take samples as directed on the procedure schedule. This is done to determine if the establishment's program or system is ensuring that the product/process meets regulatory requirements. Sample selection and submission procedures are the same as those for lot inspection.

The inspection program employees are to verify that the process control limits prescribed in the QC program or system are met and, if not, the establishment has taken action to correct the situation. To determine if the control limits are met, they evaluate the inspection sample result and compare it to the establishment's sample result(s) from the corresponding shift's production.

If the inspection sample result exceeds the establishment's process control limit, proceed as follows

Check whether the establishment found a sample result that exceeded its control limit on the same shift (not necessarily the same lot) and whether proper action was taken. If the establishment's records indicate that it had a sample result that exceeded the control limit and took proper corrective action, do not take action.

If the establishment *did not* take proper corrective action **or** its records don't indicate a sample result that exceeds its control limit, determine if the inspection sample result is in Zone E as defined in FSIS Directive 7130.3.

If the inspection sample result falls into Zone E, apply the regulatory actions for a Zone E result under normal acceptance criteria in FSIS Directive 7130.3 (see page 8 of the module).

When inspection personnel determine that an establishment has multiple, recurring noncompliance due to the establishment's failure to adequately implement immediate and further planned actions as documented on the NRs, they are to notify the District Office. **The District Office will develop enforcement strategies to deal with recurring noncompliance.**

GLOSSARY OF TERMS

Compliance Factor - A product attribute that is measured against a regulatory standard. For the purposes of this module, the compliance factors are fat, added water, and fat and added water.

Failed Lot - Any lot of product that is sampled and found to be analytically in violation of either normal or tightened acceptance criteria.

Lot - Product of one size produced from one basic formulation or specification and on one shift.

Lot Inspection - Finished product testing of a production lot for laboratory analysis. Acceptance of the lot, which represents the manufacturing process, is determined using either normal acceptance criteria or tightened acceptance criteria, depending upon sample results.

Normal Acceptance Criteria Sample - A computer-generated procedure to sample; taken at the rate of approximately once per month.

Normal Sampling - Sampling at a rate that is generated by PBIS.

Official Control Action - The application of an FSIS Form 6502-1 (U.S. Retain/Reject tag) to facilities, equipment, or product.

Plant-Requested Sampling - Sampling done at the establishment's request in addition to normal or tightened sampling to get retained product released.

Plant-Requested Sampling (Sampled Lot) - The random drawing of 30 individual 1 pound samples from a previously sampled lot that has either failed normal or tightened acceptance criteria.

Plant-Requested Sampling (Unsampled Lot) - Sampling from an unsampled lot of product produced on a shift with other lots of product subject to the same standard. One of the lots on the shift has already been sampled and found to be analytically in violation of either normal or tightened acceptance criteria.

Retained Lot - Any lot of product produced on the same shift from which a different lot (subject to the same standard) was sampled and found to be analytically in violation of either normal or tightened acceptance criteria.

Retained Shift - When an establishment is on tightened acceptance criteria, all product produced on a shift is retained.

Sample - For fat and added moisture products, a sample consists of three 1-lb units.

Sampled Lot - A lot of product, subject to the same standard as product in other lots produced on the same shift, from which a sample has been physically drawn.

Shift - The FSIS approved establishment hours of operation as specified on the plant profile, FSIS Form 5400-1.1.

Tightened Acceptance Criteria Sample - An inspection program employee-generated sample taken at the rate of once per shift. For an establishment to return to normal sampling and acceptance criteria, tightened sample results must be in Zone A for four consecutive samples. During the time on tightened sampling and acceptance criteria, a “scheduled” 05B01 procedure may be used in lieu of an inspection program employee-generated sample.

Tightened Sampling - Sampling initiated by the inspection program employee when analytical results from a sample taken at the normal rate do not meet normal acceptance criteria.

Unsampled Lot - A lot of product, subject to the same standard as product in other lots produced on the same shift, from which a sample has not been physically drawn.

Zones - Under lot inspection, sample results are categorized by statistically derived Zones A, B, C, D, or E, to reflect increasing amounts of variation in the process and possible cause for action.

SUPPLEMENT

Complete each of the following questions. You may use any source of reference available.

1. How does the inspection program employee verify that an accredited laboratory is accredited?
2. What process steps do cooked sausages in §319.180 have in common?
3. Define the following:
 - a. Normal Sampling
 - b. Tightened Sampling
 - c. Plant-Requested Sampling
4. Which laboratory sample results are recorded on the score sheet, FSIS Form 7130-3?
5. List three options, any one of which the establishment could apply to bring a sampled (failed) lot of product into compliance.
6. How many consecutive Zone C sample results require a change to tightened acceptance criteria?
7. How many consecutive sample results above Zone A require a change to tightened acceptance criteria?
8. How many consecutive Zone A sample results require a change from tightened acceptance criteria to normal acceptance criteria?
9. When would the FSIS inspection program employee select and submit 30 1-lb samples?

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Fat and Added Water in
Cooked Sausage Products
November, 1999

10. Complete the sample score sheet, FSIS Form 7130-3 on page 23. (Refer to page 16 for instructions.) For this exercise, use Establishment 38. Establishment 38 produces franks, bologna, knockwurst, and ring bologna. The establishment started out under normal acceptance criteria. All sample results are for total fat. Use the following sample results.

Item	Date Produced	Sample Number	Sample Result
Bologna	2/4/97	001	30.8
Franks	3/2/97	002	30.5
Ring Bologna	4/16/97	003	29.9
Franks	5/5/97	004	30.8
Bologna	6/5/97	005	30.1
Knockwurst	7/10/97	006	30.2
Franks	8/7/97	007	30.9
Franks	9/1/97	008	31.0
Ring Bologna	9/17/97	009	30.5
Franks	9/18/97	010	29.9
Bologna	9/20/97	011	29.8
Bologna	9/23/97	012	30.0
Franks	9/24/97	013	28.7
Ring Bologna	10/25/97	014	30.1
Knockwurst	11/12/97	015	30.5
Bologna	12/25/97	016	29.8
Franks	1/10/98	017	31.5
Franks	1/11/98	018	29.9

NOTE: For this exercise use the following zone limits from Table 1 from FSIS Directive 7130.3.

Sample Result Zones for Cooked Sausage Products
(Normal and Tightened Criteria)

Zone	Percent Fat plus Added Water	Percent Fat	Percent Added Water
A	40.0 – under	30.0 - under	10.0 – under
B	40.1 - 41.2	30.1 - 30.6	10.1 - 11.0
C	41.3 - 42.3	30.7 - 31.1	11.1 - 12.0
D	42.4 - 43.4	31.2 - 31.6	12.1 - 13.0
E	43.5 – over	31.7 - over	13.1 – over

US DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INSPECTION OPERATIONS												ZONE		PERCENT FAT PLUS ADDED WATER		PERCENT FAT		PERCENT ADDED WATER	
SCORESHEET FOR RECORD OF COMPLIANCE WITH COOKED SAUSAGE REQUIREMENTS												A		40.0 – under		30.0 – under		10.0 – under	
<input type="checkbox"/> FAT PLUS ADDED WATER <input type="checkbox"/> FAT <input type="checkbox"/> ADDED WATER												B		40.1 – 41.2		30.1 – 30.6		10.1 – 11.0	
												C		41.3 – 42.3		30.7 – 31.1		11.1 – 12.0	
												D		42.4 – 43.4		31.2 – 31.6		12.1 – 13.0	
												E		43.5 - over		31.7 – over		13.1 - over	
ESTABLISHMENT NO																			
ITEM																			
LOT #																			
DATE PRODUCED																			
SAMPLE NO																			
RESULTS (%)																			
NORMAL																			
TIGHTENED																			
ZONE E																			
ZONE D																			
ZONE C																			
ZONE B																			
ZONE A																			